IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
v.	)	NO. CR-10-216-HE
	)	
ZACHARY WILLIAMS,	)	
MICHAEL A. FELS,	)	
SHARON L. DREW and	)	
HEALTH SOLUTIONS NETWORK, LLC,	)	
	)	
Defendants.	)	

ORDER

Defendants Michael A. Fels and Sharon L. Drew are charged in a six count superseding indictment with violations of the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-904, and the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-397. Defendants filed a motion to dismiss the indictment on the grounds it fails to state an offense and the court lacks subject matter jurisdiction. In a reply brief defendants assert an additional basis for the dismissal of Counts 1 and 3-6 – lack of fair warning.

The superseding indictment alleges that defendants Williams, Fels and Drew operated White Eagle RX ("White Eagle"), a pharmacy without a valid license, filling prescriptions for internet websites such as Health Solutions Network, LLC ("HSN").[1] Count 1 charges all four defendants with conspiring to deliver, distribute and dispense fioricet, a controlled substance, by means of the internet in violation of 21 U.S.C. § 841(h)(1)(A). Count 2

[1]*According to the indictment White Eagle was "purportedly a pharmacy licensed by the Ponca Nation of Oklahoma." Superseding Indictment, p. 1.*

charges all defendants with conspiring to hold misbranded drugs for sale and to introduce misbranded drugs, specifically fioricet, a controlled prescription drug, and soma and tramadol, prescription drugs, into interstate commerce in violation of 12 U.S.C. §§ 331(a), (k) and 333(a)(2).[2] Counts 3-6 charge all defendants with distributing Fioricet, a Schedule III controlled substance.[3]

Defendants Fels and Drew contend that Counts 1, 3-6 and the forfeiture count should be dismissed because Fioricet is not a controlled substance under the CSA and that Count 2 should be dismissed because Fioricet, Soma and Tramadol were dispensed "under a valid pharmacy license issued by the Ponca Nation Tribe." Defendants' motion, p. 2. They also argue that they are exempt from prosecution with respect to all charges as they are entitled to share in the sovereign immunity of the Ponca Nation as the agents of a tribal owned business.

Fioricet

Fioricet is a combination drug containing a Schedule III controlled substance.[4] The Attorney General may "exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part" of Subchapter I of the CSA. 21 U.S.C. § 811(g). By regulation Fioricet has been designated an "exempted prescription

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[2]*Count 1 charges a § 846 conspiracy, 21 U.S.C. § 846, and Count 2 charges a § 371 conspiracy, 18 U.S.C. § 371.*

[3]*The superseding indictment also includes a forfeiture charge.*

[4]*Fioricet contains butalbital, a derivative of barbituric acid. 21 U.S.C. § 812(c), Schedule III, Part (b)(1);see http://www.justice.gov/dea/pubs/scheduling.html.*

product." 21 C.F.R. § 1308.32. The court previously considered the effect of that designation and concluded that because the exemption was "for administrative purposes only," the drug was not exempt from the application of Part D – Offenses and Penalties – of Subchapter I of the CSA (sections 401-422(a) of the Act). Having carefully considered defendants' arguments and evidentiary submissions, the court is not persuaded its initial determination was erroneous. Therefore, defendants are not entitled to dismissal of Counts 1 and 3-6 on the ground Fioricet is not a Schedule III controlled drug.

Sovereign Immunity

Citing Breakthrough Mgmt. Group, Inc. v. Chukchansi Gold Casino & Resort, 629 F.3d 1173 (10th Cir 2010) defendants claim that, as agents of White Eagle, a business owned by the Ponca Tribe, they are entitled to share in the tribe's sovereign immunity and avoid prosecution for all charges.

Defendants are not charged under any statute that is directed to Indian country, Indian tribes, or individual Indians or to situations or status unique to those circumstances. Rather, they are charged under various federal statutes of general applicability which, by their terms, apply to all persons coming within their scope. The statutes underlying the conspiracy and distributions charges are silent regarding their application to Indians or tribal entities. When a federal law of general applicability is silent on the issue of its applicability to an Indian tribe or to individual Indians, the law applies equally to Indians except where (1) the law touches "exclusive rights of self-governance in purely intramural-matters", (2) the application of the law to the tribe would "abrogate rights guaranteed by Indian treaties", or

(3) there is proof "by legislative history or some other means that Congress intended [the law] not to apply to Indians on their reservations...." United States v. Fox, 573 F.3d 1050, 1052 (10th Cir. 2009), quoting Nero v. Cherokee Nation of Oklahoma, 892 F.2d 1457, 1462-63 (10th Cir. 1989), *cert. denied*, ___ U.S. ___ (2009). *See generally* United States. v. Bruce, 394 F.3d 1215, 1220 (9th Cir. 2005) (noting, when discussing federal criminal jurisdiction over Indians and Indian country, that it had previously "held that federal criminal laws of general, nationwide applicability-such as the federal conspiracy statute, 18 U.S.C. § 371-apply to Indians unless a treaty specifically exempts them."). Here, none of the grounds for exception are present. The licensing or operation of an internet pharmacy is not a matter of internal self-governance. There is no suggestion that a treaty gives the Ponca Tribe the authority to operate an internet pharmacy outside the application of the general criminal laws. And no basis has been suggested for a conclusion that Congress did not intend for these statutes to apply to Indians or Indian tribes. Indeed, the various provisions of Title 21 plainly suggest the contrary. 21 U.S.C. § 841(h) prohibits the distribution of controlled substances "except as authorized by this subchapter...." The subchapter does not include anything that suggests a general exception for Indian tribes or their agents. The subchapter does, however, include 21 U.S.C. § 831, which sets additional requirements for online pharmacies. The definitions applicable to the subchapter contain an exception from the definition of "online pharmacy" for Indian tribes in certain limited circumstances — involving health care facilities operated by a Tribe or tribal organization pursuant to a

particular act of Congress[5] — but no other. 21 U.S.C. § 802(52)(B)(iv). Plainly, Congress knew how to carve out an exception for matters related to Indian tribes when it wanted to, but it did not do so as to the circumstances embraced by the indictment in this case.

Breakthrough, the case defendants rely on, is not to the contrary and is inapplicable. It is a civil case and has nothing to do with the reach of federal criminal laws of general applicability. Defendants are not entitled to have the charges dismissed on the basis of the Ponca Tribe's sovereign immunity.

Pharmacy License

Defendants Fels and Drew argue that the misbranding charge (Count 2) fails because White Eagle Rx held a valid pharmacy license issued by the Ponca Tribe.[6] Defendants assert that the legal impact of the Ponca Pharmacy Act and the validity of the license present questions of law, not fact.

The superseding indictment charges defendants with engaging in a conspiracy to violate 21 U.S.C. § 331(a) and (k) by introducing misbranded drugs into interstate commerce and holding misbranded drugs for sale. "A drug is 'misbranded' unless dispensed upon a "'prescription of a practitioner licensed by law to administer such drug.'" United States v. Smith, 573 F.3d 639, 650 (8th Cir. 2009) (quoting 21 U.S.C. § 353(b)(1)(C)).[7] Count 2

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[5]*The Indian Self-Determination and Education Assistance Act.*

[6]*The government responds that White Eagle did not have a valid license because the procedure for issuing a license under the Ponca Tribe of Pharmacy Act was not followed.*

[7]*(b) Prescription by physician....*
(1) A drug intended for use by man which--
(A) because of its toxicity or other potentiality for harmful effect, or the method of

alleges that the medications White Eagle mailed to customers were misbranded not just because the pharmacy was not properly licensed, but also because the drugs were not "dispensed pursuant to a valid prescription." Superseding Indictment, p. 4. A valid prescription requires a bona fide physician-patient relationship, *id.* at 652, and the superseding indictment alleges that "[t]he prescriptions were written by ... physicians who did not see or examine the customer." Superseding Indictment, p. 3. *See* United States v. Nazir, 211 F.Supp.2d 1372, 1375 (S.D.Fla. 2002) (the term prescription, as used in 21 U.S.C. § 353(b)(1) "means only a bona fide order-i.e., directions for the preparation and administration of a medicine, remedy, or drug for a real patient who actually needs it after some sort of examination or consultation by a licensed doctor-and does not include pieces of paper by which physicians are directing the issuance of a medicine, remedy, or drug to patients who do not need it, persons they have never met, or individuals who do not exist."). Therefore, even if White Eagle had a valid license, Count 2 nonetheless states a misbranding offense based on the alleged invalid prescriptions.

Due Process/Fair Warning

> *its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,*
> ....
> *shall be dispensed only (I) upon a written prescription of a practitioner licensed by law to administer such drug .... The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.*

21 U.S.C. § 353(b)(1).

Defendants assert that, if the court concludes Fioricet is a controlled substance, their prosecution under the CSA is precluded because they were not provided fair warning that their alleged conduct was unlawful. They also claim that, because of the "DEA"s unequivocal position that Fioricet is not a controlled substance," defendants' reply, p. 6, the government should be equitably estopped from criminally prosecuting them.

"[T]he Due Process Clause demands that criminal statutes describe each particular offense with sufficient definiteness to 'give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden.'" United States v. Hussein, 351 F.3d 9, 13 (1st Cir. 2003) (quoting United States v. Harriss, 347 U.S. 612, 617 (1954)). In urging the court to apply the fair-warning doctrine to the fioricet-related offenses, defendants rely heavily on United States v. Caseer, 399 F.3d 828 (6th Cir. 2005). The defendant in that case was convicted of conspiring to import, and aiding and abetting the importation of, cathinone. He appealed his conviction, claiming that the controlled substances schedules in 21 U.S.C. § 812 and 21 C.F.R. § 1308.11(f) failed to adequately put him on notice that possession of khat, a plant containing cathinone, was illegal. The Sixth Circuit noted that, while the federal regulations made it clear that cathinone is a controlled substance, neither the U.S. Code nor the Code of Federal Regulations referred to "khat," the plant from which cathinone is derived. *Id.* at 833. The Sixth Circuit distinguished Caseer "from most fair-warning cases in that the criminal provision at issue ... [was] not ambiguous in the traditional sense." *Id.* at 836; *accord* Hussein, 351 F.3d at 14-15 (defendant's due process challenge to conviction for possession of khat with intent to distribute was not typical fair warning challenge as

defendant was prosecuted under an unambiguous regulation). The asserted constitutional defect was the statute's use of a scientific term – cathinone. The Sixth Circuit concluded that "the term 'cathinone' [was] sufficiently obscure that persons of ordinary intelligence reading the controlled substances schedules probably would not discern that possession of khat containing cathinone and/or cathine constitute[d] possession of a controlled substance." Caseer, 399 F.3d at 838. However, while concerned that the defendant was not provided sufficient warning of the illegality of khat, the Sixth Circuit was "mindful of the fact that [t]he classification of a federal statute as void for vagueness is a significant matter" and that the "Supreme Court has held that every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." *Id*. at 839 (internal quotations omitted). The court concluded that "concern that a person of ordinary intelligence could unwittingly expose himself or herself to criminal penalties due to the vagueness of the controlled substances schedules with respect to khat is overcome here because ... conviction requires a showing of actual knowledge that khat contains a controlled substance." *Id.* As it determined "the requirement of specific intent ... mitigate[d] any constitutional infirmity resulting from the vagueness of the controlled substances schedules," *id.,* the court rejected Caseer's argument that the criminal provisions at issue were unconstitutional for failure to furnish fair warning.

Defendants argue that "[l]ike khat, neither Fioricet or its generic chemical composition (butalbital, acetaminophen (APAP) and caffeine) appears on the applicable drug schedule." Defendants' reply, p. 3 While Fioricet does not appear by name on the drug schedules, as mentioned earlier, it is a combination drug containing butalbital, a derivative

of barbituric acid. Both 21 U.S.C. § 812(c) and 21 U.S.C. § 1308.13(c)(3) list as a Schedule III substance, "[a]ny substance which contains any quantity of a derivative of barbituric acid." *Id.* Unlike the situation in Caseer, the issue here is not so much whether it was unclear that Fioricet was a controlled substance, but rather the effect of its being designated an "exempted prescription product." 21 C.F.R. § 1308.32. The administrator of the Drug Enforcement has stated that Fioricet would be a schedule III controlled substance but for its status as an exempted prescription product, see Doc. #175, Exhibit 7, and other DEA employees have indicated the drug is exempt from the substantive provisions of the CSA. *See e.g.*, Hassman, M.D., 75 Fed. Reg. 8194-01 (Drug Enforcement Administration February 23, 2010) (Denial of Application). Fioricet also is not included by name (unlike Fiorinal, another combination drug which contains butalbital) on the DEA, Office of Diversion Control's Controlled Substance Schedules.[8]

Under the circumstances present here, the statute and pertinent regulations "either standing alone or as construed, [do not make] it reasonably clear at the relevant time that the defendant[s]' conduct" – conspiring to distribute Fioricet and distributing Fioricet – was criminal. Caseer, 399 F.3d at 835 (quoting United States v. Lanier, 520 U.S. 259, 266-67 (1997)). Yet, like the Sixth Circuit, the court finds it unnecessary to invalidate the criminal provisions. The specific intent requirement for the crimes charged saves the statutes from potential unconstitutionality. *Id.* at 839; *see* Hussein, 351 F.3d at 13-16.

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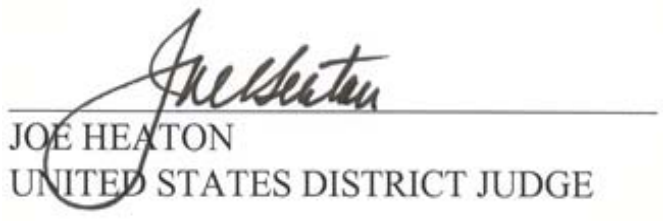
[8]*See http:// www.justice.gov/dea/pubs/scheduling.html. The DEA's list is not comprehensive. The website has a disclaimer stating that* ***"These lists are intended as general references and are not comprehensive listings of all controlled substances."***

Defendants' other basis for barring their prosecution is less persuasive. "The defense of entrapment by estoppel is implicated where an agent of the government affirmatively misleads a party as to the state of the law and that party proceeds to act on the misrepresentation so that criminal prosecution of the actor implicates due process concerns under the Fifth and Fourteenth amendments." United States v. Nichols, 21 F.3d 1016, 1018 (10th Cir. 1994). While the government may have caused the defendants and others to be confused regarding the scope of the exemption for exempt prescription products, it did not "actively mislead" the defendants. Defendants have offered no factual predicate for a valid entrapment by estoppel defense.

Accordingly, defendants Fels and Drew's motion to dismiss [Doc. #175] is **DENIED** as to all counts. The government motion to strike defendants' reply [Doc. #203] also is **DENIED**.[9]

IT IS SO ORDERED.

Dated this 14th day of September, 2011.



JOE HEATON
UNITED STATES DISTRICT JUDGE

[9]*Even though defendants failed to raise the due process issue until their reply brief, the issue merits consideration.*